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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,961

Applicant(s)

DOPSON, MINTER H.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23 and 26-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Applicant's election with traverse of the method of claim 26 in the reply filed on 1/13/06 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because the species are distinct for the reasons elaborated in the previous Office Action and the searching of additional species would place a serious burden on the Examiner..

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 24,25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/13/06.

3. Claims 23,26-31 are under consideration.

4. The amendment filed 10/26/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the addition of the phrase "incorporated by reference herein in its entirety" in newly added paragraph one, page 1 of the specification. There is no support for said statement in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. The rejection of claims 21,22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the cancellation of said claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. The rejection of claims 21 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the cancellation of said claims.

8. Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-31 are indefinite in that they depend from withdrawn claim 1. It appears that they should depend from newly added claim 23. Claims 28-30 are indefinite in the recitation of "effective amount" because it is unclear what this means in the context recited in the claim. The term "effective amount" is meaningless in the absence of a specific property to which this term refers (for example an "effective amount" to function as a biocide or prevent infection with deleterious organisms, etc).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 21,22 under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895) as evidenced by Zhang et al and Lipford et al. for the reasons elaborated in the previous Office Action are withdrawn in view of the cancellation of said claims.

11. Claims 23,26-28,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895).

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that

transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "natural egg yolk".

Regarding applicants comments, the method of Tokoro results in a product that contains transfer factor because Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor. The method disclosed by Tokoro in Example II discloses steps that the specification discloses would yield a preparation containing transfer factor (centrifugation, filtration and precipitation (see page 14)). Regarding the Dunnick et al. reference to which applicant refers, applicants comments regarding said reference have not been considered because it is not of record and a copy has not been furnished. Furthermore, as per above the name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. Claims 23,26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Anderson et al. (US Patent 6,475,527). Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "natural egg yolk". Tokoro does not disclose that the hens receive sodium chlorate. Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Tokoro teaches the claimed invention except that the hens receive sodium chlorate whilst Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). At least a portion of the administered sodium chlorate would end up in the egg. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aforementioned because Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens wherein enteric pathogens in animal food products are a problem (column 1, penultimate paragraph).

14. No claim is allowed.

15. Regarding applicants request for an interference, there are no allowed claims in the instant application for the reasons stated above.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner
Art Unit 1644


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